FINAL STATEMENT OF REASONS
TITLE 22, CALIFORNIA CODE OF REGULATIONS

SECTION 12900

USE OF SPECIFIED METHODS OF DETECTION AND ANALYSIS AS A DEFENSE TO AN ENFORCEMENT ACTION

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

PURPOSE OF REGULATION

As explained in the Initial Statement of Reasons, the purpose of new Title 22, Cal. Code of Regs., section 12900[1] is two-fold. First, the regulation will provide a "safe harbor" for persons subject to the discharge prohibition or warning requirements of the Act[2], by allowing those businesses that conduct routine tests of their discharges, releases or exposures to rely on the results of those tests, in certain circumstances, as a defense to an allegation that they are violating the discharge or warning provisions of the Act. Second, the regulation is intended to encourage businesses to pro-actively test their discharges, emissions or releases and their products for the presence of listed chemicals.

This new regulation is intended to be narrowly focused on these two objectives and does not attempt to address other scientific and evidentiary issues that may arise in a particular enforcement action. When the Office of Environmental Health Hazard Assessment (OEHHA) proposed repeal of former Section 12901 of the Proposition 65 regulations, those opposing the repeal requested that these two issues be addressed through a regulatory action, in order to provide them with a level of certainty and predictability they felt was lost through repeal of former Section 12901, and in order to encourage these businesses to continue with their Proposition 65 compliance programs.

It is important to note that this regulation does not apply where a listed chemical <u>is detected</u> in a discharge, release or exposure. In that case, the person responsible for the discharge, release or exposure would need to look to other portions of the regulations to determine whether the discharge or release contained a significant amount of the chemical or whether an exposure creates a risk significant enough to require a warning (see for example sections 12401-12504 of the regulations concerning discharges and sections 12701-12821 concerning levels of exposure to listed chemicals.)

No business is required to assert the defense offered by this regulation. It should be noted that the fact that OEHHA has referred to this regulation as an "affirmative defense" is not intended to affect the pleading provisions of Code of Civil Procedure section 431.30. OEHHA simply notes that the regulation offers a "safe harbor" defense, in certain circumstances, to an allegation that a business has violated the Act and that the burden of proof is on the business asserting the defense to establish its elements. Clarifying that the business has the burden of proving the defense if it chooses to raise it is consistent with the specific burdens imposed by the Act (Health and Safety Code sections

[1] All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.
[2] The Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.5 et seq., commonly referred to as "Proposition 65."

25249.9(b) and 25249.10(c)) and is similar to other "safe harbor" provisions of the Proposition 65 regulations (see for example Section 12501).

Finally, as specified in subsections (a) and (e) of Section 12900, this regulation should not be construed to limit in any way the admissibility of evidence offered by plaintiff's or defendant's in Proposition 65 enforcement actions, except to the extent that the defense has been properly pled and proved.

PROCEDURAL BACKGROUND

On February 18, 2005, OEHHA issued a Notice of Proposed Rulemaking announcing that OEHHA was proposing to adopt an addition to the Proposition 6 regulations, specifically; new Title 22, California Code of Regulations, Division 2, Chapter 3, Section 12900. A public hearing was held on April 4, 2005 to receive comments on the proposed regulation. Comments were received orally at the public hearing and in writing during the 45-day public comment period. An extension of 14 days was provided based on requests from interested parties for an extension of the public comment period. The extended comment period closed on April 18, 2005.

Following review of the oral and written comments on the proposed regulation, OEHHA amended the proposed regulatory text that was originally released in the February 18 notice and provided notice on July 8, 2005 of a 45-day comment period on the amended proposed regulation. This second comment period closed August 22, 2005. Based upon the additional written comments that were received on the amended proposed regulation, OEHHA further amended the proposed regulatory text. A second notice of modifications to the text was issued on October 28, 2005, initiating a third 15-day comment period that closed on November 14, 2005. Six written comments were received during this comment period. In response to those comments OEHHA made further amendments to the proposed regulations and noticed a fourth public comment period beginning on December 16 and ending on January 9, 2006.

UPDATE OF THE INITIAL STATEMENT OF REASONS

Explanation of the Substantive Changes in the First Amended Text (July 2005)

OEHHA made the following substantive amendments to the proposed regulation in response to the comments received during the first 45-day comment period. Other non-substantive, editorial changes were also made that are not separately discussed here, but are reflected in the underline/strike-out version of the proposed regulation.

All definitions for terms and phrases in the regulation were grouped together and placed at the end of the regulation in subsection (g) for clarity and readability.

Title

The title of the regulation was changed to reflect the fact that the regulation is intended to offer a defense in an enforcement action.

12900(a)
Subsection 12900(a)**,** was modified to more closely track the statutory language of Proposition 65 and to clarify that the regulation provides an affirmative defense to either in an illegal discharge (Health and Safety Code section 25249.5) or a failure to warn (Health and Safety Code section 25249.6) enforcement action (or both) and that all four criteria listed in the regulation must be met in order for a defendant to successfully assert the defense.

The criteria that must be met in order to assert the defense in subsection (a)(1), was numbered for clarity and readability.

Language was added to subsection (a) to clarify that the method of detection and analysis applied must be applicable to the chemical in question and must be applied to the appropriate matrix. The provision requiring that the testing be conducted "in good faith" based on comments indicating that such a provision is subjective would be difficult to prove or disprove in an enforcement action.

The term "medium" was replaced throughout the regulation beginning in subsection (a), with the term "matrix" and a definition for that term was added in subsection (g) to better describe what must be tested.

A provision was added to subsection (a)(3) in response to public comments and requires that testing be conducted by a state certified laboratory to establish a minimum baseline of competency for a laboratory.

The provision in subsection (a)(4) requiring that "each and every such test conducted at any time during that year" was deleted and replaced with the word "all" for clarity and readability. The words "no detectable level" and "present" in the same subsection were replaced with the words "not detected" for clarity and readability.

12900(c)
An amendment was made to allow for the use of a method of detection and analysis required by permit even if it is not the most sensitive test method available that meets the criteria in the regulation. This change was made in response to comments and is more consistent with the stated purposes of the regulation described previously.

12900(d)
Language was modified in the subsection to clarify that all <u>material</u> requirements of a particular method of detection and analysis must be followed. This change was made based on comments received by OEHHA that indicated the former language was unrealistic and might prevent a business from using an accurate test result where a minor mistake had been made that did not affect the accuracy of the test method or procedure.

12900(g)
All definitions that had been included in the original proposal, along with an additional definition for the term "matrix" were gathered together into this subsection to improve clarity and readability of the regulation.

The definition of the term "matrix" was developed based upon discussions with Department of Toxic Substances Control staff at the Hazardous Materials Laboratory in Berkeley, California. OEHHA believes this is an accurate definition for the term and more closely describes the substance or material that must be used for testing under this regulation than the former term (i.e. "medium").

Explanation of the Changes in the Second Amended Text (October 2005)

A cross-reference error was corrected. Reference to subsection (f) should have been to subsection (g).
OEHHA also made one substantive amendment to the proposed regulation in response to the comments received during the second 45-day comment period. The following text was added to subsection (a)(3):

> "…or accredited by the State of California, a federal agency, the National Environmental Laboratory Accreditation Program or similar nationally recognized accrediting organization to perform the particular method of detection and analysis in question…"

This addition was made in response to concerns expressed in the public comments that the proposed requirement that a business use a laboratory certified by the State of California was too restrictive. This addition is intended to provide more flexibility for businesses in selecting a laboratory to conduct testing, while still maintaining the requirement for an adequate level of competency for the laboratory in the particular test methodology being applied.

It should be noted that a business could use foreign laboratories that become certified or accredited as required by this subsection for testing. There is no express requirement that the laboratory be physically located in the United States, only that the laboratory, wherever it may be located, meets the same standards applied to domestic laboratories.

Explanation of Changes in the Third Amended Text (December 2005)

In response to comments received during the final 15-day comment period, a non-substantive change was made in subsection (c) to clarify that the permit being referenced in this subsection must be specific to the business relying on it. The phrase "<u>that person's</u>" was added for clarity. This additional text does not substantively change the purpose or intent of the proposed regulation.

Also in response to a comment, an additional federal agency, the <u>U.S. Consumer Products Safety Commission</u>, was added to the federal agencies already listed under subsection (a)(3). This addition does not change the purpose or intent of the regulation. It simply adds an additional source of possible methods of detection and analysis.

The word "affirmative" was deleted from the title of the proposed regulation to avoid the possible incorrect impression that OEHHA was making a statement concerning the pleading requirements of Code of Civil Procedure section 431.30.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF FEBRUARY 18, 2005 THROUGH THE EXTENDED DATE OF APRIL 18, 2005

Please refer to Appendix 1 attached hereto and incorporated by this reference.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE SECOND NOTICE PERIOD OF JULY 8, 2005 THROUGH AUGUST 22, 2005

Please refer to Appendix 2 attached hereto and incorporated by this reference.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE THIRD NOTICE PERIOD OF OCTOBER 28, 2005 THROUGH NOVEMBER 14, 2005

Please refer to Appendix 3 attached hereto and incorporated by this reference.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE FOURTH NOTICE PERIOD OF DECEMBER 16, 2005 THROUGH JANUARY 9, 2006

One comment letter was received from the law firm of McQuaid, Bedford & Van Zandt, LLP during this comment period. That letter is summarized below, along with OEHHA's responses to those comments.

Comment 1: OEHHA should consider the court's ruling in the *As You Sow v Conbraco Industries et al* [3]case and integrate some of the findings the court made in interpreting former Section 12901 of the Proposition 65 regulations into this new regulation.

Response: Pursuant to Title 2, Cal. Code of Regs, section 11346.9(a)(3), since this comment does not specifically address the three changes to the proposed regulation that were the subject of the notice or the procedures used by OEHHA in proposing the regulation, no response is required. However, OEHHA notes that the *Conbraco* case was specifically decided based upon former Section 12901 and should be read in the context of that regulation.

Comment 2: The letter goes on to reiterate several issues already raised in previous comments that have already been responded to and are not restated here, these include a request that OEHHA specifically include the International Association of Plumbing and Mechanical Officials and the American National Standards Institute under Subsection (a)(3) of the proposed regulation, a request that OEHHA adopt specific test methodologies for various Proposition 65 listed chemicals, a concern that Section 12900's requirement that a chemical not be detected and that the test used must be the most sensitive among those meeting the criteria is too restrictive and may require a business

[3] __Cal.Rptr.3d ___, 2005 WL 3366955 (Cal.App. 1 Dist. Dec. 12, 2005), rehearing denied January 4, 2006.

to "prove a negative," that the requirement that a test be conducted within one year prior to the filing of a notice or complaint is too short a time frame and that OEHHA should provide a "compliance period" by delaying the effective date of the regulation.

Response: All these issues were raised previously and are discussed in the summaries and responses to comments for the earlier public comment periods. Pursuant to Title 2, Cal. Code of Regs, section 11346.9(a)(3), since these comments do not specifically address the three changes to the proposed regulation that were the subject of the notice or the procedures used by OEHHA in proposing the regulation, no additional response is required.

ALTERNATIVES DETERMINATION

OEHHA has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation. Some alternative language provided in responses to comments was incorporated into the final regulation. These provisions are described above or in the specific responses to comments included in the three appendices. Similarly, other language proposed in the public comments was not included because it either did not add clarity to the regulation or was inconsistent with the purpose, intent, or scope of the regulation. These proposed amendments, and the reasons there were not accepted, are discussed in the specific responses to comments included in the three appendices.

This new regulation is intended to address core needs for clarity and certainty concerning testing methodologies already in use by California businesses and were specifically requested by business representatives in order to assist them in their compliance efforts. The proposed regulatory action does not impose any new requirement upon affected businesses. Instead, the regulation establishes a "safe harbor" defense, under specified circumstances, to allegations that a person doing business may have violated the Act. No business is required to assert the defense offered by the regulation. Therefore, it cannot be seen as imposing any new duty on business that is mandatory.

LOCAL MANDATE DETERMINATION

Pursuant to Health and Safety Code Section 25249.11(b), the provisions of Proposition 65 do not apply to local, state or federal agencies. The proposed regulation does not impose any mandate on local agencies or school districts.